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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,245	08/18/2003	David R. Fischell	MR3065-19	2995

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

NOTIFICATION DATE	DELIVERY MODE
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12/09/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptoactions@rkpatlaw.com
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Office Action Summary	Application No. 10/642,245	Applicant(s) FISCHELL ET AL.	
	Examiner George R. Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 40-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-36, 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37 and 40-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Claims 1-36 and 48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/25/09.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37 and 40-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is assessing cardiac function “based upon the amplitude of the electrical signal at a sample defined by the R waves and the first particular offset time” in combination with the other elements in the claims. Claim 37 seem to be broadening the original scope by, at the minimum, just using an amplitude of a sample at an offset time. This scope was originally not set forth in the original specification and is considered new matter. The original specification dealt with determining cardiac ischemia using more elements to assess the condition of the heart, such as multiple points, averages, baselines, subtraction of points, etc (e.g. page 37 of the specification and others).

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37 and 40-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is vague and the Examiner can not determine which elements are being positively recited, which elements are being functionally recited, and what the claim is accomplishing or claiming.

In claim 37, in the preamble the claim is to "A system" but then states "for assessing cardiac function using...., the system comprising". The use of "for" makes the "assessing" functionally recited, but the use of "using" makes the claim vague since it is unclear if the system positively recites/includes those elements after "using" or if it part of the functional "for". If the elements after "using" are being positively recited it is suggested to use "the system comprising" or "the system including". The examiner has interpreted every element in the preamble after "for" and "using" to line 6 to be functionally recited. If this is incorrect the applicant should state so on the record and change the claim language accordingly.

In the claim, "R-R interval", "QRS fiducial points", "of R-R intervals", "R-R intervals", "R wave", "the R-R interval" and "the R waves" are used. It is unclear whether these are the same elements, different elements, and some the same and some different elements, etc. It is suggested to clarify each of the R's by maybe using an identifier before each, such as "current", "a first", "a second", "a user selected", etc. and then refer back to the identifier, such as "the current R-R interval" to clarify which element is being discussed.

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In step (a), "having a corresponding plurality of R-R intervals" is vague. It is unclear if these R-R intervals are also inputted, if the offset times naturally have corresponding R-R intervals, or if the system somehow matches the received offset times with R-R interval sets already in the system. If the R-R intervals are also being inputted, it is suggested to delete "having" and insert "and receiving".

In step (b), to clarify the R-R intervals, it is suggested to maybe use "means for detecting current R-R intervals" if that is what is meant to be claimed. If what is meant to be claimed is actually determining the interval between R waves, then the claim language should be changed accordingly.

In step (c), "relative to a sample within an R wave" is vague. Does this refer to a sample in line 4 or a different sample. If it is the same sample then "the sample" or "a sample of the digital samples" should be used. If it is a new sample then the claim should set forth an element to take a sample. In line 2 of (c), "an Rwave" must be clarified. Does this refer to the R-R intervals of the preamble or step (b) or something else? In lines 3 and 4 of (c), the particular offset time is first stated to be based on the R-R interval and then stated to be based on the user selected offset. It is unclear if the particular offset time needs to be based on both or one or the other. If it is both, then it is suggested to state "based on both the R-R interval... and at least one of the first plurality of ...".

In step (d), "at a sample defined by..." is vague and it is unclear if this is the same sample used in the preamble, step (c), or a new sample. It is also vague since it is unclear how the sample is "defined" by the R-waves. What does this mean. In line 2, "the R-waves" lacks antecedent basis.

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Claim 45 is vague for using (a), (b), and (c) since they have already been used in claim 37. In addition, the steps are vague (see the 112 second rejection for claim 37 above).

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

GRE
12/4/09